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|--|-------------|----------------------|---------------------------|------------------|
| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.       | CONFIRMATION NO. |
| 10/727,217   | 12/03/2003  | Mark B. Chidlaw      | PC9858A                   | 4494             |
| 28523 7590 01/26/2007<br>PFIZER INC.<br>PATENT DEPARTMENT, MS8260-1611<br>EASTERN POINT ROAD<br>GROTON, CT 06340 |             |                      | EXAMINER<br>TRAN, SUSAN T |                  |
|  |             |                      | ART UNIT                  | PAPER NUMBER     |
|  |             |                      | 1615                      |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE   |             | MAIL DATE            | DELIVERY MODE             |                  |
| 3 MONTHS   |             | 01/26/2007           | PAPER                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/727,217             | CHIDLAW ET AL.      |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Susan T. Tran          | 1615                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>all</u> . | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Claim Objections***

Claim 19 is objected to because of the following informalities: the word "making" in line 2 appears to be a typographical error.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is rejected in the use of the improper Markush language. The claim recites (i), (ii), (iii), (iv), (v), (vi), or (vii). A proper Markush language is (vi) *and* (vii).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 and 9-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faour US 6,004,582.

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Faour teaches a process for preparing an osmotic dosage form comprising an active core (5), a semipermeable membrane (4), a water-soluble polymer coat (3), and an immediate release active agent-containing external coat (2) (column 4, lines 63 through column 6, lines 1-13; and Fig. 2). The claimed active agents can be found in columns 13-15). Faour further teaches the dosage form is suitable to deliver one or more active agents to an environment of use in a controlled manner (abstract; column 1, lines 4-22; and column 5, lines 1-3). Semipermeable membrane includes cellulose acetate and polyethylene glycol (column 4, lines 24-34; column 9, lines 1-27; and examples). Faour further teaches a taste masked finish coating (8) (column 17, lines 58-64; and examples).

Faour does not explicitly teach the claimed properties, such as the time to release 50% of the active agent into the use environment is at least 0.5 fold, but less than 2.0 fold the time required for the composition to release 50% of said active agent into a control use environment comprising less than about 0.1% dietary fat. Faour further does not teach the percent amount of dietary fat in the use environment.

However, it is noted Faour teaches the use of the claimed polymeric coating, e.g., cellulose acetate, in a similar osmotic dosage form for a controlled release of active agent to the same use environment, such as GI tract. Accordingly, the use of identical structures necessitates similar properties desired by the applicant. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are

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necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). When the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Thus, one of ordinary skill in the art would have been motivated to, by routine experimentation modify the controlled release osmotic dosage form of Faour to obtain the claimed invention, because Faour teaches using similar polymeric coating for the same purpose, namely to deliver active agents to the use environment in a controlled manner.

Claims 8 and 9-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faour US 6,004,582, in view of FDA press release or Camden US 6,136,835.

Faour is relied upon for the reason stated above. Faour does not expressly teach a dosage form with a written matter indication.

FDA press release teaches an improved package inserts that include boxed warning, indications and usage, and dosage and administration (page 2). FDA press release further teaches the improved package inserts provide safe an optimal use of drugs, which improves health outcomes for patients and more efficient delivery of healthcare (page 1).

Camden teaches a pharmaceutical composition comprising a container, a dosage form, and a printed instructions either as an inserts or as labels, indicating quantities of the components to be administered, guidelines for administration (column

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20, lines 1-15). Thus, it would have been obvious to one of ordinary skill in the art to prepare a dosage form and includes a written indications to provide guideline for administration, because it is required by the FDA, and because it is well known in pharmaceutical art.

### ***Pertinent Arts***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Faour is cited as of interest for the teaching of using cellulose acetate as a polymeric coating.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'S. Tran', is written over the printed name and title.

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SUSAN TRAN  
PRIMARY EXAMINER